specimens with SFC with sensitivity 83% and specificity 86%.
Conclusion IF at λ_x=480 nm identifies SFC in plaques with high content of PG and SMC and in thin fibrous cap atheromas.

ORAL CONTRIBUTIONS

820 Novel Approaches to Percutaneous Coronary Intervention With Emphasis on Saphenous Vein Grafts

Monday, March 31, 2003, 2:00 p.m.-3:30 p.m.
McCormick Place, Room S401

2:00 p.m.

820-1 A Prospective, Randomized Trial of Thromboatherectomy During Intervention of Thrombotic Native Coronary Arteries and Saphenous Vein Grafts: The X-TRACT Trial

Gregg W. Stone, David A. Cox, Joseph D. Babb, Dean Nukta, Luc Bilodeau, Louis Cannon, Thomas D. Stuckey, James Hermiller, Eric Cohen, Reginald Low, Alexandra J. Lansky, Steven R. Bailey, Richard E. Kuntz, Cardiovascular Research Foundation/Lenox Hill Heart and Vascular Institute, New York, NY

Background. Peri-procedural complications are increased during PCI of SVGs and native coronary arteries containing thrombus. Whether outcomes may be improved by thrombectomy prior to intervention is unknown.
Methods. At 75 U.S. sites, 800 consecutive pts with diseased SVGs (72%) or native coronary lesions containing thrombus (28%) were prospectively randomized to standard PCI vs. thromboatherectomy with the ev3 X-SIZER followed by PCI. Randomization was stratified by IIb/IIIa use.
Results. Baseline clinical and angiographic characteristics were well matched, except that by core lab determination X-SIZER patients were more likely to have thrombus present (70% vs. 58%, p<0.001), and had a slightly greater initial diameter stenosis (70% vs. 67%, p<0.05). GP IIb/IIIa inhibitors were administered in 78% of each group. Rates of post procedure TIMI flow, no reflow and distal emboli were similar in the 2 groups. Among pts not receiving upfront IIb/IIIa inhibitors, bail-out IIb/IIIa use was required in fewer patients treated with the X-SIZER (2.1% vs. 10.3%, p=0.02). The 30-day composite major adverse cardiac event rate (death, MI, or TVR) was similar in pts treated with X-SIZER vs. control (17.0% vs. 17.4% respectively, p=NS). The X-SIZER did, however, lower the pre-specified rate of large MI (Q-wave MI or peak CPK-MB >8x nl) by 41% (5.5% vs. 9.6%, p=0.03). After accounting for the difference in baseline thrombus and lesion severity by multivariate analysis, use of the X-SIZER was an independent predictor of freedom from large MI (odds ratio = 0.35, p=0.002) and death or large MI (OR = 0.43, p=0.006).
Conclusions. Performance of thromboatherectomy with the X-SIZER prior to PCI in diseased SVGs or thrombotic native coronary lesions does not reduce the overall 30 day composite rate of adverse events. X-SIZER use does, however, reduce procedural complications as evidenced by less need for bail-out GP IIb/IIIa inhibitors, and enhances 30-day survival free from large MI.

2:15 p.m.

820-2 Treatment of Saphenous Vein Bypass Grafts With Ultrasound Thrombolysis: A Randomized Study

Mandeep Singh, Uri Rosenscheim, Kalon K. Ho, Peter B. Berger, Richard Kuntz, David R. Holmes, Jr., Mayo Clinic, Rochester, MN

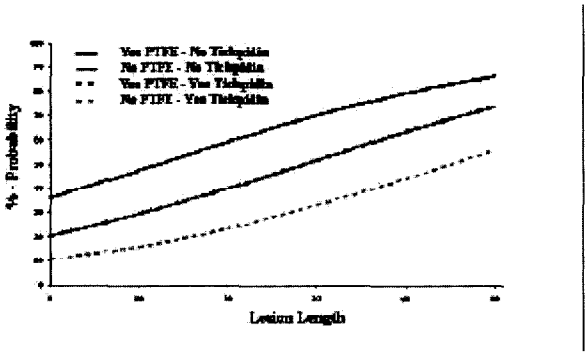
Background Percutaneous coronary interventions (PCI) in patients with saphenous vein grafts (SVG) have a high frequency of distal embolization and other adverse clinical events, particularly if thrombus is present. Acolysis (therapeutic ultrasound) has the ability to break up thrombus *in vitro,* in animal models, and in humans. Whether this is beneficial during percutaneous SVG interventions is unknown.
Objective We performed a randomized trial of Coronary Ultrasound Thrombolysis (CUT) in which patients with an acute coronary syndrome undergoing PCI in a SVG were randomly assigned to receive treatment with acolysis or therapy with abciximab. The primary end point of study was a successful procedure without complications at 30 days defined as a final luminal diameter stenosis ≤30% by quantitative angiographic analysis with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow and freedom from major adverse cardiac events (MACE- a composite of death, Q and non-Q-wave myocardial infarction, emergency bypass surgery, disabling stroke, and target lesion revascularization) at 30 days.
Results. One hundred and eighty one patients, 92 randomized to acolysis and 89 to abciximab, were enrolled. The two groups were well matched for baseline and lesion characteristics. Angiographic procedural success was achieved in 63% of patients randomized to acolysis and 82% randomized to abciximab (p=0.008). The cumulative incidence of MACE at 30 days was 25% in the acolysis vs. 12% in the abciximab group (p=0.036), due mainly to a greater frequency of non-Q-wave myocardial infarction (19.6% vs 7.9%, p=0.03) in patients treated with acolysis. The incidence of Q-wave myocardial infarction was also higher in patients treated with acolysis (5.4% vs 2.2%, p=NS). The primary end point was thus achieved in 53.8% of acolysis and 73.1% of abciximab patients (p=0.014).
Conclusions In this randomized trial, use of therapeutic ultrasound in vein graft lesions in patients with acute coronary syndrome was associated with poor angiographic outcome and increased the incidence of acute ischemic complications.

2:30 p.m.

820-3 Predictors of Adverse Clinical Outcome in the Randomized Evaluation of Covered Stent in Saphenous Vein Graft (RECOVERS) Trial

Goran Stankovic, Antonio Colombo, Fabio Sgura, Flavio Airoldi, Carlo Briguori, Nicholaous Reifart, Patrizia Presbitero, Luigi Inglese, G. Heyndrickx, Carlo Di Mario, EMO Centro Cuore Columbus, Milan, Italy, San Raffaele Hospital, Milan, Italy

In the Randomized Evaluation of Covered Stent in Saphenous Vein Graft (RECOVERS) trial polytetrafluoroethylene (PTFE) covered stent was compared with stainless steel (SS) stent for prevention of major adverse cardiac events (MACE) for treatment of saphenous vein graft (SVG) lesions. The results of this trial have already been presented. We aimed to determine clinical, angiographic and procedural predictors of adverse 6-month clinical outcome.
Methods and results: 292 pts were randomized to PTFE JOSTENT (152 pts) and SS JOSTENT Flex (140 pts). Pts received aspirin and ticlopidine for 3 months. MACE were defined as death, myocardial infarction (MI) and repeat revascularization. Cumulative 6-month MACE rate was 31% in PTFE group vs 19% in SS group (P=0.01), with MI rate of 14% vs 5.5% (P=0.02).
Multivariate analysis identified following predictors of MI: prior stroke (coeff -2.46, P=0.006), ref. vessel size (coeff. -1.52, P=0.003), stent length (coeff. -0.11, P=0.02), final min. lumen diameter (coeff 1.21, P=0.03). Predictors of cumulative MACE were: use of PTFE stents (coeff 0.78, P=0.02), lesion length (coeff -0.05, P=0.02) and trend was found for compliance to 3-month ticlopidine therapy (ceof 0.76, P=0.09). Figure shows calculated probability of MACE according to lesion length, compliance to 3 month ticlopidine therapy and use of PTFE stents. Conclusion: Use of PTFE covered stents to treat long SVG lesions and non-compliance to ticlopidine therapy negatively affects six-month clinical outcome.



2:45 p.m.

820-4 A Prospective Randomized Multicenter Trial Comparing Distal Protection During Saphenous Vein Graft Intervention With a Filter-Based Device Compared to Balloon Occlusion and Aspiration: The FIRE Trial

Gregg W. Stone, Campbell Rogers, James Hermiller, Robert Feldman, Patrick Hall, Robert Haber, A. Masud, Patrick Cambier, Ronald P. Caputo, Mark Turco, Richard Kovach, Bruce R. Brodie, Howard Herrmann, Richard Kuntz, Steve Ramee, David A. Cox, Cardiovascular Research Foundation/Lenox Hill Heart and Vascular Institute, New York, NY

Background. Percutaneous intervention (PCI) in diseased saphenous vein grafts (SVG) is associated with a high peri-procedural rate of complications. Distal protection during SVG PCI using a balloon occlusion and aspiration system (the PercuSurge GuardWire) has been shown in a large randomized trial to reduce 30 day MACE rates by 42%. Compared to balloon occlusion systems, filter-based distal protection devices may be simpler to use, and allow antegrade perfusion during the procedure, reducing ischemia time and facilitating intervention in pts with poor LV function. The absolute clinical efficacy of distal filters as an adjunct to PCI in diseased SVGs has not been proven, however, nor has their relative efficacy compared to balloon occlusion/aspiration systems.
Methods. We therefore performed a large, multicenter non-inferiority trial of PCI in diseased SVGs in which 650 consecutive pts at 65 U.S. and Canadian centers were randomized 1:1 to intervention with distal protection using the BSC/EPI FilterWire EX vs. the PercuSurge GuardWire. The FilterWire consists of a microporous polyurethane net attached to a self-expanding nitinol ring anchored distally to a 0.014' guidewire over which PCI is performed. Crossing profile is 3.9F. Randomization was stratified by use of IIb/IIIa inhibitors, the administration of which was left to the discretion of the operators. The primary endpoint was the composite rate of death, MI (CPK-MB >3x nl), CABG or target lesion revascularization at 30 days.
Results. The last patient was enrolled in August, 2002. Pooling the pts, the mean age was 69± 10 years, 21% were female, 31% had prior MI, 39% had diabetes, 82% hypertension, 86% hyperlipidemia, and 12% renal insufficiency. Baseline LVEF was 49% ± 12%. The mean graft age was 11 ±6 years.
Conclusions. FIRE is the first completed large-scale randomized trial comparing filter-

based distal protection to balloon occlusion and aspiration during PCI of diseased saphenous vein grafts. The principle safety and efficacy data will be unblinded for presentation in March 2003.

3:00 p.m.

820-5 Economic and Clinical Analysis of Elective Percutaneous Coronary Intervention Without On-Site Cardiac Surgery

Kirsten Hall Long, Henry H. Ting, Erin K. Mc Murtry, Aaron S. Terry, Thomas H. Tiggelaar, Ryan J. Lennon, Kirk N. Garratt, Mandeep Singh, Charanjit S. Rihal, Douglas L. Wood, David R. Holmes, Mayo Clinic, Rochester, MN

Background: Elective percutaneous coronary interventions (PCI) are routinely performed at hospitals with on-site cardiac surgery (CS). Since 1999, elective PCI has been performed at Immanuel St. Josephs Hospital (ISJ), a community hospital without on-site CS, with telemedicine support from Saint Marys Hospital (SMH).
Methods: 215 PCI patients at ISJ were matched on clinical and lesion criteria to 430 PCI patients at SMH. Clinical outcomes assessed included procedural success (<20% residual stenosis and without in-hospital death, myocardial infarction, coronary bypass surgery, or repeat PCI), and target vessel failure rates at 1 year (any death, myocardial infarction, or target vessel revascularization). Economic outcomes included billed charges for room and board, medications, supplies, laboratory, and hospital length of stay.
Results: Procedural success rates were similar between groups (ISJ 99.0%; SMH 97%). Target vessel failure rates were also similar between groups at 1 year follow-up (ISJ 16%; SMH 16%, P=0.80). Results of the economic comparison are shown in the table. Patients undergoing PCI at ISJ had significantly higher charges for medication and supplies reflecting higher utilization of stents (93% versus 86%) and glycoprotein IIb/IIIa inhibitors (88% versus 57%).
Conclusions: Favorable clinical outcomes can be achieved at a hospital without on-site CS at additional cost. Economic analyses are ongoing to assess the relative cost-effectiveness of providing PCI without on-site CS.

Economic Endpoints (2000 Constant Dollars)

	ISJ (mean)	SMH (mean)	Bootstrapped 95% CI (mean difference)	P-value
Room and Board	$2422	$2341	(-183, 346)	0.64
Medications	$2602	$1147	(1299, 1610)	<0.0001
Laboratory	$1731	$1401	(164, 486)	0.0009
Supplies	$5013	$3861	(698, 1564)	0.0001
Length of Stay	2.34 days	2.23 days	(-0.173, 0.378)	0.49

3:15 p.m.

820-6 Genetic Risk Diagnosis System for Restenosis After Percutaneous Coronary Intervention

Hideo Izawa, Yoshiji Yamada, Hideki Horibe, Tomoko Kato, Sahoko Ichihara, Fumimaro Takatsu, Toyoaki Murohara, Mitsuhiro Yokota, Nagoya University Graduate School of Medicine, Nagoya, Japan, Gifu International Institute of Biotechnology, Mitake, Japan

Background: Although genetic epidemiological studies have suggested that several genetic variants increase the risk for restenosis after percutaneous coronary intervention (PCI), the genes that contribute to this condition remain to be identified definitively. Our aim was to develop a reliable system for genetic risk diagnosis of restenosis after either plain old balloon angioplasty (POBA) or stent implantation separately.
Methods: Restenosis was evaluated for 1390 (910 in men, 480 in women) and 1001 (710 in men, 291 in women) coronary lesions 6 months after successful POBA or stent implantation, respectively. The genotypes for 19 or 18 single nucleotide polymorphisms (SNPs), which we previously identified in an association study of 112 polymorphisms in 71 genes with 445 patients with myocardial infarction and 464 controls, were determined in men and women, respectively, with a fluorescence- or colorimetry-based allele-specific DNA primer-probe assay system.
Results: Multivariate logistic regression analysis with adjustment for age, body mass index, and the prevalence of smoking, hypertension, diabetes mellitus, hypercholesterolemia, and hyperuricemia revealed that six and five SNPs were associated with restenosis after POBA or stent implantation, respectively, both in men and in women. Combined genotype analysis yielded maximal odds ratios of 15.09 and 44.54 for restenosis after POBA and of 6.64 and 117.83 for in-stent restenosis in men and women, respectively.
Conclusions: Ten and seven genes are susceptibility loci for restenosis after PCI in Japanese men and women, respectively, and the corresponding combined genotypes may prove reliable for determination of genetic risk for restenosis after POBA or stent implantation. This genetic risk diagnosis system is thus expected to contribute to the prediction of restenosis after PCI.

ORAL CONTRIBUTIONS

823 Percutaneous Intervention: Highlighted Biologic and Pharmacologic Adjuncts

Monday, March 31, 2003, 2:00 p.m.-3:30 p.m.
McCormick Place, Room S402

2:00 p.m.

823-1 Improvement in Symptoms and Exercise Capacity at Eight Weeks in a Controlled Study of Autologous Bone Marrow Cell Transplant in Humans With Severe Ischemic Heart Failure

Emerson C. Perin, Hans F. Dohmann, Radovan Borojevic, Andre Luiz S. Sousa, Hans J. Dohmann, Antonio C. Carvalho, Yong J. Geng, Guilherme V. Silva, Fernando Rangel, Suzana A. Silva, Roberto Esporcatte, James T. Willerson, Texas Heart Institute, Houston, TX, Hospital ProCardiaco, Rio de Janeiro, Brazil

Background: Relatively limited treatment options exist for pts with severe ischemis heart failure (HF). We evaluated the safety and efficacy of transendocardial (TE) delivery of bone marrow mononuclear cells (BMNC) to treat pts with severe HF.
Methods: Fourteen pts (57.2 ± 10.5 yrs, 11 males) with severe LV dysfunction by echo (EF 27 ± 8 %) and severe CAD not amenable to revascularization were included. Pts were evaluated by exercise stress tests before and 8 wks after the procedure. Bone marrow (50ml) was aspirated from the iliac crests and BMNCs were isolated. TE injections were performed using the Myo-Star catheter (NOGA, Biosense) to target hibernating myocardium in 10 pts. Four pts were followed without cell implants as a control group.
Results: Events: There were no major in-hospital events. Minor events included transient hypotension with pulmonary congestion (n=1) and PVCs (n=1) on day 1. CK-MB levels did not increase in 24h. Late events in the BMSC group included 1 pt that had NSTMI at 7 days. In the Control group 1 pt died at 8 wks. **Non-invasive F/U:** In the BMNC group NYHA functional class decreased from 2.2±0.8 to 1.2±0.4 compared to an increase 2.3± to 2.5± in the control group (p<0.0004). Exercise times increased from 7.45 ± 1.97 to 9.00± 0.2 min.in the treatment group vs. 7.42±0.48 to 4.26±2.00 in the control group. SPECT results will be presented.
Conclusion: Preliminary results suggest that TE delivery of BMNCs is safe and feasible. In this high risk and small group of pts we have observed symptomatic benefit and improvement in treadmill exercise time. Further studies and follow-up are needed.

2:15 p.m.

823-2 Glycoprotein IIIa PIA Polymorphism and Early Outcome After Coronary Stenting in Patients With Adjunctive Abciximab Therapy

Nicolas von Beckerath, Olga Gorchakova, Werner Koch, Julinda Mehilli, Petra Hoppmann, Adnan Kastrati, Albert Schomig, TU München, Munich, Germany

Background: PI^A polymorphism of glycoprotein (GP) IIIa has been intensively investigated. We and others have reported that homozygous PI^{A2} carriage is associated with an increased risk of early thrombotic events following coronary artery stenting. In those studies only few or no patients had received abciximab. One purpose of this study was to test if the prothrombotic influence of the PI^{A2} allele after coronary stenting persists in the presence of potent antiplatelet therapy with abciximab. The second purpose was to test whether PI^{A2} polymorphism that underlies most cases of alloimmunethrombocytopenia occurring in caucasians is associated with thrombocytopenia in response to abciximab.
Methods: Consecutive patients (n=2265) undergoing coronary stent implantation with adjunctive abciximab therapy were included in the study. Serial platelet counts were obtained (baseline, 8, 16, 24, 72h post intervention and before discharge) and in case of a platelet count < 100 000/µl pseudothrombocytopenia was excluded or confirmed. GP IIIa PI^A genotyping was performed with a TaqMan assay. Thrombotic events (death, myocardial infarction and stent thrombosis) were recorded during the first 30 days following stent implantation. Acute profound thrombocytopenia was defined as a true drop in platelet count to < 20 000/µl within 24h.
Results: The overall genotype distribution was 2.8% $PI^{A2/A2}$, 26.7% $PI^{A2/A1}$ and 70.5% $PI^{A1/A1}$. Early thrombotic events were observed in 4.8% of $PI^{A2/A2}$, 5.0% of $PI^{A2/A1}$ and 5.4% of $PI^{A1/A1}$ patients (P=0.88). Acute profound thrombocytopenia developed in 14 patients (1 $PI^{A2/A2}$, 7 $PI^{A2/A1}$ and 6 $PI^{A1/A1}$). Thus, carrying PI^{A2} was afflicted with a threefold increase of the risk to develop acute profound thrombocytopenia (OR 3.2 [95% CI, 1.11-9.30]).
Conclusions: Adjunctive abciximab therapy appears to eliminate the previously described prothrombotic influence of the PI^{A2} allele in the setting of coronary stenting. PI^{A2} carriers, though, have an increased risk to develop acute profound thrombocytopenia in response to this therapy.